

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Wang et al.
Appl. No.: 10/598,909
Conf. No.: 1906
Filed: September 14, 2006
Title: DELIVERY OF FUNCTIONAL INGREDIENTS
Art Unit: 1655
Examiner: Q. Mi
Docket No.: 0112701-00753

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:

I obtained B.S. degree and Master degree in Chemical Engineering from Dalian Polytechnic University (DPU), China. In 1993, received PhD in Chemistry from Swiss Federal Institute of Technology Zurich (ETH-Z). In the same year, I joined Nestlé Research Centre (NRC) in Lausanne. Since 2005, I was leading the Bioactives & Micronutrients Group, where my responsibility was to develop natural extraction technologies and concepts of bioactive delivery for healthy and tasty foods. Since July 2010, I have been appointed as the head of Nestlé Research Centre Beijing, to conduct nutrition research to promote bone&joint, cardiovascular and metabolic health.

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated November 16, 2010 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the references cited therein, JP 09107880 to Osanai ("*Osanaï*"), in view

of Journal of Agricultural and Food Chemistry to Edenharder et al. ("*Edenharder*"), Eur J. Nutr to Faulks et al. ("*Faulks*") and Royal Society of Chemistry to Hovari et al. ("*Hovari*") and further in view of JP 2003164261 to Imazawa et al. ("*Imazawa*"), as well as the pending claims.

4. Independent Claims 1, 12 and 14 recite, in part, a miscible primary composition comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable material, plant material and combinations thereof, excluding insoluble fibers, in a carrier selected from the group consisting of milk, milk protein-containing carriers and combinations thereof. The essential lipophilic and hydrophilic bioactive components are extracted from the material by milling the material in the milk or milk protein-containing carrier and the insoluble fibers are removed by centrifuging the carrier after milling. Moreover, the miscible primary composition is stable, miscible and dispersible in an aqueous system.

5. Conventional techniques for extracting such bioactive components only extract some of the bioactive components from the fruit or plant material. Water extraction techniques, in which the bioactive components are extracted from insoluble fibers, preserve the natural image and nutritional functions of the bioactive components but are not very efficient. Solvent extraction techniques, while more efficient than water extraction, still fail to extract a substantial portion of the bioactive components from the fruit or plant material and simultaneously impair the nutritional functions of the bioactive components. Therefore, traditional water and solvent extraction techniques are only able to extract a few compounds of the fruit or plant material, leaving some other bioactive materials in the remaining material. For example, polysaccharides, polyphenols and other non-lipophilic compounds are not extracted together with the lipophilic components such as carotenoids, lipophilic vitamins and other lipids.

6. The claimed compositions are produced by processes that allow for the extraction of a greater amount of bioactive materials than with traditional water or solvent extraction techniques. The fruit or plant material is mixed in a milk or milk protein-containing medium and separated from insoluble fibers to obtain an aqueous suspension. By using a milk or milk

protein-containing carrier to extract the bioactive components from the fruit or plant material and centrifuging the milk or milk protein-containing carrier, the present claims provide compositions having bioactive components with improved miscibility, stability and bioavailability over conventional extraction techniques without the use of organic solvent residues. By using milk or milk proteins, soy-milk or milk-like proteins from plants, the claimed compositions provide a similar profile of the important nutrients like the whole fruit.

7. The inventors have surprisingly found that milling the material contained in the milk or milk protein-containing carrier allows for the formation of much smaller particles of ground plant material, allowing more efficient access by the milk or milk protein-containing carrier to both the water-soluble and oil-soluble bioactives of the plant material. Moreover, Applicants have found that the proteins in the milk or milk protein-containing carrier are significant for the increased extraction of the lipophilic and hydrophilic bioactive components from the plant material. Furthermore, centrifuging the milk or milk protein-containing carrier after milling of the fruit or plant materials removes the insoluble fibers and further provides the claimed composition as a whole to be stable, miscible and dispersible in an aqueous system.

8. *Osanai* fails to disclose or suggest a miscible primary composition comprising a milk-based carrier that is stable, miscible and dispersible in an aqueous system as required by independent Claims 1, 12 and 14. *Osanai* discloses a beverage containing cow's milk, rapa gourd, spinach and lemon, among other ingredients. It is noteworthy that each of the embodiments of the beverage disclosed by *Osanai* at least includes approximately 22.5 grams of lemon. Moreover, lemon is an essential aspect of *Osanai's* beverage as it supplies vitamin C in an amount that is not satisfied with the remaining elements of the beverage. See *Osanai*, paragraph 12.

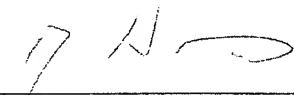
9. An experiment was performed to determine the impact of lemon on cow's milk as taught by *Osanai*. The experiment showed that the addition of 22.5 grams of lemon to 100 ml of milk led to a precipitation/coagulation of a large portion of the milk proteins in the milk causing an obvious lack of miscibility. See Exhibit A. Therefore, upon experimental testing to compare

Osanai's beverage against the claimed invention, it is clear that *Osanai* does not provide a miscible primary composition that is stable, miscible and dispersible in an aqueous system according to the claimed invention.

10. In sum, the inventors have surprisingly found that the milk proteins are essential for the improved extraction of the lipophilic bioactive components according to the claimed invention. The claimed miscible primary composition comprising a milk-based carrier that is stable, miscible and dispersible in an aqueous system provides the optimal conditions for extracting the most lipophilic bioactive components from plant materials. In contrast, because of the precipitation/coagulation of a large portion of the milk proteins in the beverage of *Osanai*, these precipitated or coagulated proteins are immiscible in solution and are no longer free to extract the lipophilic bioactive components of plant materials. This reduces the effectiveness of the extraction and the amount of the extracted bioactive components that could end up in the beverage. As a result, the miscible primary composition of the claimed invention is a distinguishable product over the immiscible beverage resulting from the components and process of *Osanai*.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 2011-05-06



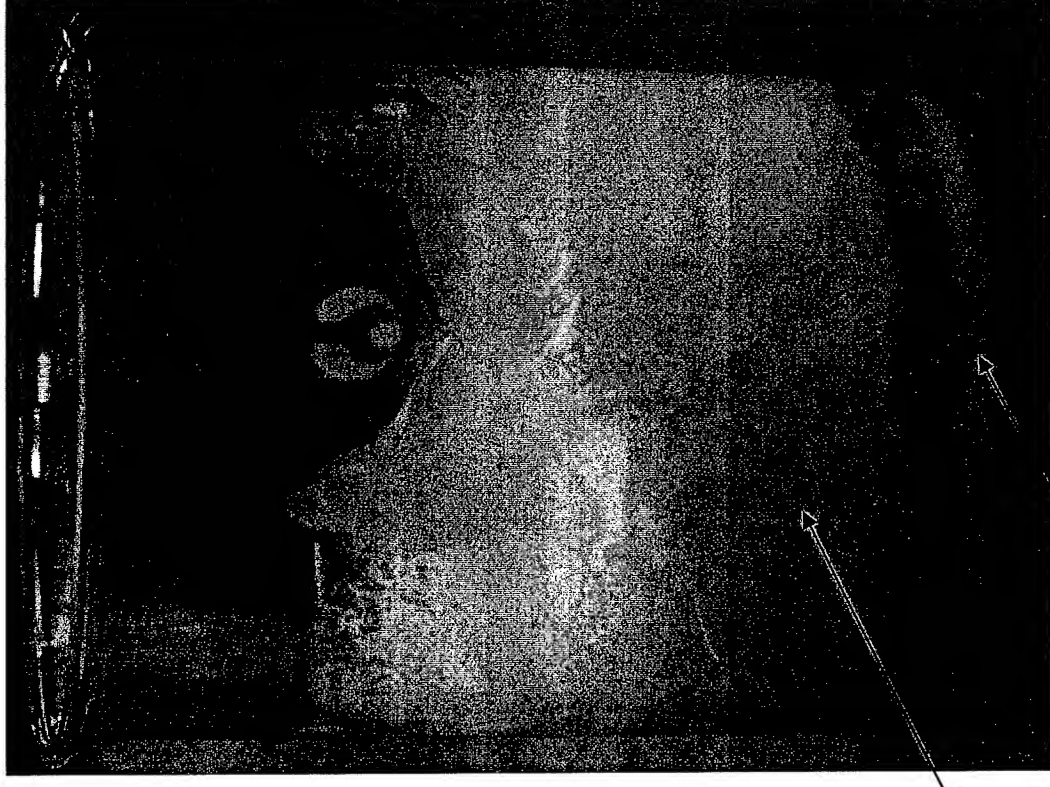
Print Name Junkuan Wang

EXHIBIT A

Milk mixed with lemon according to the Osanai instruction:
(no other vegetables were added)

1. Lemon 22.5g mixed with 100mL cow's milk (Nestle UHT milk commercial product).
2. Add extra cow's milk (Nestle UHT milk commercial product) to adjust the sun total to 200mL.
3. Picture was taken after sample being kept quiescent for 10 minutes.
- 4 . Product pH is 4.26 @ 25C

Milk + lemon



foam

Protein precipitate